K062857

KLS martin L.P.

510(K) SUMMARY

NOV 2 2 2006

Submitter:	KLS-Martin, L.P. 11239-1 St. Johns Industrial Parkway South Jacksonville, FL 32246 Phone: 904-641-7746 Fax: 904-641-7378
Contact Person:	Jennifer Damato Director RA/QA
Date of Summary:	9 September 2006
Device Name:	KLS Martin Quick Disc
Trade Name:	Quick Disc
Common Name:	Plate, Cranioplasty
Classification Name and Number:	Preformed Nonalterable Cranioplasty Plate (CFR 882.5330)
Regulatory Class:	II
Predicate Devices:	CranioFix Titanium Clamp System (K040864) Spin Down RapidFlap (K031034) OsteoMed Cranial Flap Fixation System (K022277) Synthes Cranial Flap Twist Clamp (K991860) Aesculap CranioFix Titanium Clamp System (K972332)
Intended Use:	The KLS Martin Quick Disc is intended for use in the reattachment of cranial bone flaps after a craniotomy, covering burr holes, and fixation of cranial fractures.

Device Description:

The KLS Martin Quick Disc is a two-sided cranial closure device. The lower disc is attached to a threaded post. The upper disc is threaded down and locked on the post securely holding the bone flap in place. The KLS Martin Quick Disc diameters range from 12mm to 22mm in size

Technological Characteristics:

Similarities to Predicate

The KLS Martin Quick Disc is similar in intended use, material composition and principle as the CranioFix Titanium Clamp System (K040864), Spin Down RapidFlap (K031034), OsteoMed Cranial Flap Fixation System (K022277), Synthes Cranial Flap Twist Clamp (K991860), and Aesculap CranioFix Titanium Clamp System (K972332). The KLS Martin Quick Disc is similar in fixation as the Aesculap CranioFix Titanium Clamp System (K972332)

Substantial Equivalence:

The KLS Martin Quick Disc is substantially equivalent in intended use, material composition and principle to the CranioFix Titanium Clamp System (K040864), Spin Down RapidFlap (K031034), OsteoMed Cranial Flap Fixation System (K022277), Synthes Cranial Flap Twist Clamp (K991860), and Aesculap CranioFix Titanium Clamp System (K972332).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

KLS Martin, L.P
% Ms. Jennifer Damato
11239 St. Johns Industrial Parkway South
Jacksonville, Florida 32246

NOV 2 2 2006

Re: K062857
Trade/Device Name: KLS Martin Quick Disc
Regulation Number: 21 CFR 882.5330
Regulation Name: Preformed nonalterable cranioplasty plate
Regulatory Class: Class II
Product Code: GXN
Dated: September 9, 2006
Received: September 25, 2006

Dear Ms. Damato:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0210 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: KLS Martin Quick Disc

Indications For Use:

The KLS Martin Quick Disc is intended for use in the reattachment of cranial bone flaps after a craniotomy, covering burr holes, and fixation of cranial fractures.

Prescription Use ✔ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062857